Serial No.: 09/905,017 Filed: July 13, 2001

REMARKS

In the Office Action of August 26, 2004, the Examiner issued a final rejection of all pending claims 1-12, 14 and 19. Claims 1-8, 12 and 14 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,700,253 ("Parker"), and further in view of U.S. Patent 5,462,523 to Samson ("Samson I").[1] Claims 9-11 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of Parker, Samson I and U.S. Patent 6,053,903 ("Samson II"). Applicant respectfully requests reconsideration and reexamination of the application in view of the following remarks.

The present application is directed to a medical device comprising a tube having a coil in a stressed, radially expanded condition, a braid extending over at least part of the coil, and a polymeric layer positioned over and contacting at least the coil. The polymeric layer maintains the coil in its stressed radially expanded condition. The medical device is particularly applicable for various uses that require small diameter structures, such as in the expansion of a narrowed or obstructed bodily passage, as a conduit for introducing a medicament or other medical device therethrough, or as a sheath for providing access deep into the vascular system of a patient.

Since the inventive device includes both a coil and a braid, it receives the particular advantages of each. It is known that the use of a coil in a medical sheath increases the flexibility of the device, and inhibits kinking. Flexibility of a sheath, particularly at the distal end, is generally an important feature of a sheath. This is particularly true when the sheath is to be used to access tortuous passageways. For a sheath to be able to bend in those passageways without kinking, the sheath material on the outer part of the bend must be able to stretch, and the corresponding sheath material on the inner part of the bend must compress. When a coil is incorporated into a sheath, the distance between the coil turns on the outside of the bend can elongate or increase very easily with minimum force, thereby allowing the sheath to stretch at said outer bend portion. At the same time, the distance between the turns on the inside of the coil decreases, allowing the sheath to compress at said inner bend portion. As a result, a coiled sheath achieves the flexibility to navigate the tortuous bends, and then revert back to its original shape.

A braid, on the other hand, comprises overlapping woven fibers or filaments. The woven nature of a braid causes it to resist substantial expansion and compression of the type that occurs

[1] The final Office Action indicates that claims 20 and 21 were also subject to this rejection. However, claims 20 and 21 had been previously cancelled in Applicant's amendment mailed May 3, 2004.

with a coil. Therefore, a braid does not exhibit the degree of flexibility and kink resistance associated with a coil. Rather, a braided structure is known to provide favorable pushability, trackability and torqueability, when compared to a coiled structure. Thus, in those applications wherein torque must be supplied to a sheath to force it through passageways, the woven nature of a braid makes it superior to that of a coil for such use.

Those skilled in the art recognize that although braids and coils are each capable of providing beneficial attributes to a sheath, the two types of structures address different problems that may be encountered when attempting to pass a sheath through the vasculature. The present invention advantageously combines the advantages of each, by providing a device that incorporates both a braid and a coil. In addition, the coil and sheath are specifically arranged in the medical device in a manner to obtain greater benefit from each. For example, the inventive device can be constructed to have portions of different flexibility. This can be achieved by varying the durometer of the outer polymeric layer from one section to another, or by extending the coil distally beyond the distal end of the braid, thereby maintaining the flexibility and kink resistance at the tip that is provided by the coil, and separating this flexible distal section from the relatively more stiffer and more torqueable section that includes the coil/braid combination.

In the final Office Action, the Examiner cited the primary Parker reference as teaching a device having a coil in a stressed radially expanded condition. The Examiner acknowledged that Parker does not teach a braid extending over the coil. Samson I was cited for teaching a braid extending over a coil. The Examiner stated that it would have been obvious to combine the teachings of Parker and Samson I because "according to Samson the braid will provide extra support for the coil and allows for better maneuverability of the catheter tip." Applicants respectfully disagree with the Examiner's characterization of the Samson I reference, and submit that when properly construed, this reference is not a proper citation against the present claims.

As specified by the Examiner, the cited Parker patent teaches a sheath that includes a coil compression fitted around the inner liner of the sheath. The sheath does not include a braid, nor does the patent include any suggestion for incorporating a braid into the sheath. Since the outer tube in Parker melts and connects to the inner tube through the turns of the coil, one skilled in the art might expect that a braid would be particularly inappropriate for the Parker structure, because the presence of a braid would inhibit the flow of the melted outer tube through the coil turns. Failure of

flow between the coil turns would prevent the mechanical connection of the outer tube to the inner liner, and thereby defeat the express and intended purpose of the patent. The inventive device need not include an inner liner, therefore there is no concern that the connection between the outer tube to an inner liner might be insufficient. Rather, the coil is stretched in a stressed, radially expanded condition and maintained in that condition during formation. Torsional control is not a subject of the cited Parker patent, and enhanced torqueability would not normally be achieved by the Parker structure.

The Samson I patent, titled DRUG DELIVERY SYSTEM, relates to the field of medical perfusion. The delivery catheter taught therein is used for delivering a medicament to a target site within the body by perfusion, through a plurality of openings along the distal tip of the perfuser. The tip section that includes the openings includes two primary components, namely an inner stiffener portion which is relatively porous, and an outer perfuser layer which controls the flow of the fluid through the perfusion openings. The inner stiffener may be a coil, and the outer perfuser layer may be a braided tube, although other embodiments indicate that a certain amount of interchangeability is possible between the coil and the braid. In fact, one embodiment includes two braids, and does not even include a coil. Selected filaments of the braided tube are removed to provide openings to enable controlled perfusion therethrough. Col. 3, line 61 to Col. 4, line 4. The coil and the braid are cooperatively arranged in a manner such that they provide the series of openings through which an agent, such as a liquid, can pass from the interior of the device to the exterior environment. This structure is not provided to enhance the flexibility or torqueability of the perfuser tip, and in fact, the presence of the coil/braid structure as taught does not appear to enhance the flexibility or kink resistance of the perfuser tip. The fact that the coil and braid are interchangeable, and that the coil may even be omitted altogether, indicates that these structures are provided for reasons other than to enhance flexibility and torqueability. In fact, it appears that they are provided to establish a structure from which perfusion openings can be easily created and controlled. Flexibility and torqueability, if they are considerations of the perfuser tip at all, are at best collateral features.

In applying the Samson I reference, the Examiner stated that Samson I teaches that the braid will provide extra support for the coils and allows for better maneuverability of the tip. Applicant respectfully disagrees with the Examiner's characterization of Samson I. It is true that Samson I

describes a catheter that is purported to be maneuverable (using a guidewire) into tight portions of the body's vasculature. However, to the extent that it exists, any such maneuverability is provided by the flexible portion of the catheter body structure 108, and not by the coil/braid of the perfuser tip section 110. According to the specification of Samson, catheter body 108 is constructed according to the prior art structure disclosed in U.S. Patent No. 4,739,768 to Engelson, cited by Samson at Col. 4 of his patent. The Engelson patent discloses a catheter structure comprising a relatively stiff proximal segment, an intermediate segment that is more flexible than the proximal section, and a distal segment that is most flexible. The differences in flexibility are achieved by altering the particular polymers that comprise each of these segments, from a relatively stiff polymer at the proximal end to a relatively flexible polymer at the distal section. When the Engelson construction is incorporated in Samson's catheter, the flexible distal portion [of the catheter body] "... near the perfusion tip (110) is the most flexible. In this way, the catheter assembly may be maneuvered using a guidewire into very tight portions of a body's vasculature." (Col. 4, lines 28-31). Thus, the flexibility and maneuverability of the Samson device is provided by the distal portion of catheter body 108 (which is constructed according to Engelson), and not by the braid of the perfuser tip 110 as indicated by the Examiner in the Office Action in her statement supplying the rationale for applying this reference.

Applicants also take issue with the Examiner's contention that, according to Samson I, the braid will provide extra support for the coil. The gist of the Samson teaching is that the *coil* provides support for the perfuser *braid*, not the other way around. See, e.g., Col. 4, lines 41-43. Fig. 7 of Samson does show an alternate embodiment wherein a braided inner stiffener is provided. Although this braided stiffener may provide some support to the device, in this instance the braided stiffener is surrounded by a coil. This arrangement is opposite to that of the claimed invention wherein the braid extends over the coil.

For the foregoing reasons, Applicants respectfully submit that the Examiner's rationale for applying Samson I is misplaced, and reconsideration of the rejection of the claims is respectfully requested. Applicants have previously provided their reasons why the references cited herein are not properly combinable, which comments need not be repeated herein.

Based on the foregoing, the Applicants respectfully assert that the application is in condition for allowance. Accordingly, Applicants respectfully request the issuance of a Notice of Allowance.

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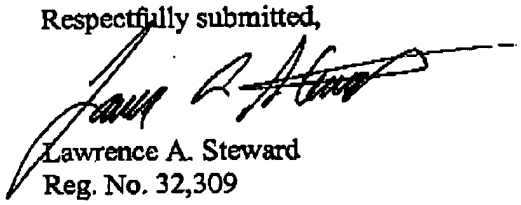
If the Examiner believes that prosecution of this application would be advanced by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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